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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,646	01/13/2005	Berta Kotar Jordan	4061-2SPUS	9299
27799	7590	12/30/2009	EXAMINER	
COHEN, PONTANI, LIEBERMAN & PAVANE LLP			COLEMAN, BRENDA LIBBY	
551 FIFTH AVENUE			ART UNIT	PAPER NUMBER
SUITE 1210				1624
NEW YORK, NY 10176				
		MAIL DATE	DELIVERY MODE	
		12/30/2009	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/521,646	<b>Applicant(s)</b> KOTAR JORDAN ET AL.
	<b>Examiner</b> Brenda L. Coleman	<b>Art Unit</b> 1624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(o).

#### Status

- 1) Responsive to communication(s) filed on 09 September 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-28 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 6-28 is/are allowed.  
 6) Claim(s) 1-5 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
     Paper No(s)/Mail Date \_\_\_\_\_
- 4) Interview Summary (PTO-413)  
     Paper No(s)/Mail Date \_\_\_\_\_
- 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-28 are pending in the application.

This action is in response to applicants' amendment dated September 9, 2009.

#### ***Response to Arguments***

Applicants' arguments filed September 9, 2009 have been fully considered with the following effect:

1. With regards to the 35 U.S.C. § 102(b), anticipation rejection of claims 1-5, 10, 11 and 25, labeled paragraph 1) maintained in the last office action. The applicants' arguments have been fully considered, however they were not found persuasive. The Applicants' stated that Form I discussed in Bunnell is actually form II defined in the present application. The applicants' stated that the present application adopts the definition of Form I and Form II provided by EP-B-733635. However, there is no indication of this in the applicants' disclosure that Form I of the instant invention is Form I or Form II. In the absence of the specific x-ray diffraction pattern to describe the invention, i.e. Form I, the applicants' claims are rejected under 35 U.S.C. § 102(b) as set forth herein and in the reasons of record. The applicants' further indicated that EP 831098, WO 01/47933 and WO 02/18390 indicate Form I which has an x-ray powder diffraction pattern such that the first point is 9.9463. It is noted that the references cited by the applicant indicate Form I is 9.9463 and Form II is 10.2689, however there are references such as Bunnell et al., U.S. Patent No. 5,703,232 where the x-ray powder diffraction pattern for Form I is 10.2689 and Form II is 9.9463 as set forth in Cochran et al., U.S. Patent No. 7,229,643; Beasley, Jr., U.S. Patent No. 6,780,433; Tran, U.S.

Patent No. 6,506,746; McIntosh et al., U.S. Patent No. 6,432,943; Beasley, Jr., U.S. 5,776,928; etc. and since there are references with varying x-ray powder diffraction patterns for "Form I" and "Form II" thus as stated in the last office action the rejection of Claims 1-5 is herein maintained as long as there is no clarification on the record as to what the applicants compound is, i.e. "Form I".

Claims 1-5 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bunnell et al., U.S. Patent No. 5,703,232, for reasons of record and stated above.

***Allowable Subject Matter***

2. Claims 6-28 are allowed. None of the prior art of record or a search in the pertinent art area teaches the solvates, Form A of olanzapine and process of preparing anhydrous forms and Form A of olanzapine as claimed herein.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/  
Primary Examiner, Art Unit 1624